

K002261

OCT 23 2000

**510(k) Summary**

**MR-III**

**Date Prepared: July 24, 2000**

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**A. Submitter**

Smith & Nephew, Inc.  
Endoscopy Division  
160 Dascomb Road  
Andover, MA 01810

**B. Company Contact**

Demetrios Tsakonas  
Clinical/Regulatory Specialist

**C. Device Name**

Trade Name:	MR-III
Common Name:	Suture Retention Device Suture, Nonabsorbable, Polyester
Classification Name:	Suture Retention Device (KGS) Suture, Nonabsorbable, Synthetic, Polyester (GAS)

**D. Predicate Devices**

T-Fix previously cleared by K925573 and K942442.

**E. Description of Device**

The MR-III is a suture retention device manufactured from polyester suture, polyacetal bar, stainless steel needle and a plastic handle.

**D. Intended Use**

MR-III is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue repair.

The indications for the MR-III are for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as shoulder stabilization (Bankart Repair), rotator cuff repair, meniscal repair and gastrostomy.

**E. Comparison of Technological Characteristics**

Both the T-Fix and the MR-III are intended to be used to fixate soft tissue by anchoring the tissue internally from a single access point and securing the suture by a knot.

Demetrios Tsakonas

*Demetrios Tsakonas*

*Clinical/Regulatory Specialist*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 23 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Demetrios Tsakonas  
\*Clinical/Regulatory Specialist  
Smith & Nephew, Inc.  
Endoscopy Division  
160 Dascomb Road  
Andover, Massachusetts 01810

Re: K002261  
Trade Name: MR-III  
Regulatory Class: II  
Product Code: GAS  
Dated: July 24, 2000  
Received: July 25, 2000

Dear Mr. Tsakonas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

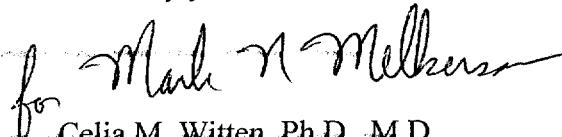
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Demetrios Tsakonas

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K002261

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510(k) Number :

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Indications for Use :

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-the-Counter

(Optional Format 1-2-96)

for Mark M. Muller

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K002261